PMA/510(k) Expedited Review – Guidance for Industry and CDRH Staff

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Office of Device Evaluation, Program Operations Staff

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Until June 29, 1998, comments and suggestions regarding this document should be submitted to Docket No. 98D-0173, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 12420 Parklawn Drive (HFA-305), Room 1-23, Rockville, MD 20857. Such comments will be considered when determining whether to amend the current guidance.

After June 29, 1998, comments and suggestions may be submitted at any time for Agency consideration to, Program Operations Staff, Kathy Poneleit for PMA Expedited Review and Heather Rosecrans for 510(k) Expedited Review, 9200 Corporate Blvd., HFZ-402, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Kathy Poneleit, 301-594-2186, KMP@cdrh.fda.gov or Heather Rosecrans, 301-594-1190, HSR@cdrh.fda.gov.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

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Purpose[1]

The criteria and procedures under which expedited review would apply to Premarket Approval Applications (PMAs), PMA Supplements, and Premarket Notifications (510(k)s)(hereinafter referred to as applications) for medical devices were previously identified in General Program Memorandum #G94-2, "PMA/510(k) Expedited Review." In order to reflect the criteria in Section 515(d)(5) of the act, as modified by Section 202 of the FDA Modernization Act of 1997, entitled "Special Review for Certain Devices," the above named guidance is being modified and replaced by this guidance. The modifications include rearranging the first three criteria and revising the fourth to track the new statutory language more closely. All other sections of this document track the now rescinded General Program Memorandum #G94-2, "PMA/510(k) Expedited Review."

Introduction

These procedures are based on the Management Action Plan (MAP) initiative paper entitled "PMA/510(k) Expedited Review Process." This guidance embodies the procedures flowing from that issue paper and implements the principles in that document as the policy of the Office of Device Evaluation (ODE). This guidance will be used by ODE reviewers in applying these procedures to the review of incoming applications.

FDA believes it is in the interest of the public health to review applications for certain medical devices in an expedited manner. Expedited review will generally be considered when a device offers a potential for clinically meaningful benefit as compared to the existing alternatives (preventative, diagnostic, or therapeutic) or when the new medical device promises to provide a revolutionary advance (not incremental advantage) over currently available alternative modalities.

Granting of expedited review status means that the marketing application would receive priority review before other pending applications, i.e., the application will be placed at the beginning of the appropriate review queue. If multiple applications for the same type of medical device offering comparable advantage over existing approved alternatives have been granted expedited review, they will be reviewed with priority according to their respective submission due dates.

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Once one of the applications is approved, those of the same type still pending will generally lose their expedited review status with regard to review resources but will retain their place in the review queue.

Except as specifically noted, applications under expedited review would be subject to all other controls and requirements applicable to comparable applications in the standard review process. Accordingly, valid scientific evidence, as defined by Title 21 of the Code of Federal Regulations, should be used to support an application subject to expedited review. This evidence will generally be obtained from well designed, monitored, and controlled clinical trials, when appropriate, so that the medical device may be evaluated as promptly and efficiently as possible.

Criteria

In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, ODE will consider expedited review for devices which: (1) are intended to treat or diagnose such diseases or conditions and (2) meet at least one of the following criteria:

1. The device represents a breakthrough technology. The medical device represents a clear, clinically meaningful advantage over existing technology. A clear clinically meaningful advantage is defined as having major (not incremental) increased effectiveness or reduced risk compared to existing technology. In order to meet this criterion, the device should have been evaluated utilizing well defined, clinically meaningful outcome measures or acceptable surrogates for such measures.

2. No approved alternative exists. That is, no legally marketed diagnostic/therapeutic modality is available for the intended patient population.

   NOTE: Applications in this category that are granted expedited review status will not only be placed at the beginning of the review queue, but will also undergo accelerated evaluation as review staff are available to be assigned.

3. The device offers significant advantages over existing approved alternatives. This criteria would apply to a device which provides for clinically important earlier diagnosis or offers important advances in safety and/or effectiveness over existing alternatives.

4. The availability of the device is in the best interest of the patients. For a device to meet this criterion, it is expected that the device would provide a specific public health benefit or meet the need of a well-defined patient population. For example, this criterion would apply to a device designed or modified to address an unanticipated serious failure occurring in a critical component of an approved device for which there are no alternatives, or for which alternative treatment would entail substantial risk of morbidity for the patient.

Procedures

1. Identification of Applications for Expedited Review. Each ODE reviewing Division will identify those applications which meet the criteria for expedited review, either during the IDE stage, through pre-submission meetings with the applicant, or through a preliminary evaluation of the submitted application.

   Sponsors are encouraged to identify early in their correspondence with the Center devices that they feel meet the criteria for expedited review listed above.

2. Determination of Expedited Review. The ODE Division Director will authorize the decision to expedite review within the following time frames:

   510(k)s - The decision to expedite review should be made within 30 days from the receipt date of the application.

   PMAs - and PMA Supplements - FDA will consider granting expedited review at anytime for PMAs and PMA supplements. For example, an applicant may make the request to the Division prior to the PMA or PMA supplement submission. Review staff should take the opportunity during the 45 day filing review and decision period to determine if expedited review has already been granted or if it should be granted. For PMAs and panel-track supplements, the filing or not filing letter will reflect the expedited review decision if requested as part of the PMA submission or if previously granted, will reflect the decision of that determination.

   Should expedited review be granted to a competing product, all other products for that intended use should generally be granted expedited review status until one of the applications becomes approved for that intended use.

   Requests for expedited review of a PMA supplement should be evaluated upon receipt of the supplement. A letter notifying the applicant of the expedited review decision should be issued within 30 days of receipt of the PMA supplement.

3. Documentation and Processing. After this determination has been made, the Division will prepare a written memo to the administrative record that highlights, using the criteria outlined above, the reasons why the marketing application has received expedited review status. A copy of this memo should be provided to the Director, ODE, and the 510(k) or PMA Section of the Program Operations Staff. The Division will prepare and issue a letter, based upon the current boilerplate letter provided by the POS Staff, notifying the applicant of the expedited review status. The notification conveying expedited review status may be incorporated in filing letters. A copy of the letter should be forwarded to the POS office for inclusion in the official administrative file and for updating databases. A letter should also be issued to the applicant if the 510(k) or PMA is later removed from expedited review status.

4. Resource Management. It will be the responsibility of the Director of the reviewing Division to ensure that the application is reviewed in the most efficient manner, tracked as an expedited review, and completed within the statutory time frames. It is recognized that implementation of this policy may impact other review work of the Division. Additional resources may be necessary for review of the marketing applications granted expedited review. All of the following resource issues should be considered to accommodate the expedited review process:

   a) a shift in the workload within the affected reviewing Division may be necessary;

   b) scientists from other Divisions or from outside of ODE may be called upon to provide support to those areas in ODE where the standard review queue would otherwise be affected by the needed redistribution of the workload; and

   c) review of the other non-expedited applications in that reviewing Division may be delayed.

   In a separate memo to the Director, ODE, for each application that will receive expedited review, the Division should:

   a) discuss the level of concerted effort the application will require, i.e., a list of the types of reviewers necessary (medical officers, biologists, engineers, etc.) and the level of participation these reviewers will have in the review of the application;

   b) designate who will be the lead reviewer; and

   c) identify the displaced workload, e.g., briefly describe the lead reviewer(s)' current workload and the applications that will have to be redistributed.

5. Monitoring. The Office of the Director, ODE, will periodically review, approximately every 90 days, decisions to expedite review to provide feedback to the Division Directors regarding consistency of decision making within and among Divisions.

6. Public Disclosure. The fact that an application has been reviewed under these expedited procedures will be first disclosed to the public only at the time of PMA approval or 510(k) clearance.

   A publicly disclosable paragraph should be provided to appropriate media outlets and FDA information sources (OST computer bulletin board, DSMA, etc.) so that interested outside parties may determine what types of applications have been granted expedited review.